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February 11, 2021

VIA E-MAIL and ECF
The Honorable Thomas I. Vanaskie
Special Master for Discovery
Stevens & Lee
1818 Market Street, 29th Floor
Philadelphia, PA 19103

Re: *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*, U.S. District Court for the District of New Jersey; Case No. 1:19-md-02875-RBK-KMW

Dear Special Master Vanaskie:

On behalf of Defendants' Executive Committee[1], we appreciate the opportunity to submit the following overview of the proceedings in the above-referenced litigation.

I. THE PARTIES AND CLAIMS

These cases arise out of certain voluntary recalls of generic medications containing the active pharmaceutical ingredient ("API") valsartan, and to a lesser extent, losartan and irbesartan, which were found to contain nitrosamine impurities. To date, the litigation has focused on claims and discovery relating to valsartan, and the losartan and irbesartan claims are in a prefatory posture. Defendants are various entities involved in bringing generic valsartan medications to the U.S. market[2], and fall into five distinct groups—API manufacturers (including API distributors), finished dose manufacturers (including finished dose distributors), and the so-called "Downstream Defendants," third-party distributors and

[1] Defendants' Executive Committee includes Lori Cohen of Greenberg Traurig LLP, Seth Goldberg of Duane Morris LLP, Clem Trischler of Pietragallo Gordon Alfano Bosick & Raspanti, LLP, Jeffrey Geoppinger of Ulmer & Berne LLP, and Sarah Johnston of Barnes & Thornburg LLP. Defendants' Liaison Counsel includes Seth Goldberg and Jessica Priselac of Duane Morris LLP. *See* [Dkt 96] Case Management Order No. 6 Approving Plaintiffs' and Defendants' Leadership Structure.

[2] Defendants Hetero USA, Inc., and Prinston Pharmaceutical, Inc., serve only as FDA liaisons for other entities that fall into the five groups enumerated here. Notably, some of the Defendants fall into more than one group.

wholesalers, repackagers, and retailers. There are three categories of plaintiffs asserting claims here: personal injury plaintiffs who allegedly ingested Defendants' valsartan and claim their valsartan contained nitrosamines and thus caused them cancer; medical monitoring (putative class action) plaintiffs who allegedly ingested valsartan and claim an increased risk of cancer; and economic loss (putative class action) plaintiffs who include both consumers and third-party payers who allegedly paid for valsartan and claim it was "worthless" due to the impurity, despite having received full therapeutic benefit and suffering no personal injury.[3] Plaintiffs' Master Complaints assert every conceivable common law and statutory product liability and consumer loss cause of action, including punitive damages. Currently there are 748 active cases, and as described below, Defendants deny any liability on multiple factual and legal grounds including, but not limited to, general and specific causation.

II. PRODUCTS AT ISSUE

The valsartan containing drugs ("VCDs") at issue are the generic versions of certain branded angiotensin II receptor blocker ("ARB") drugs approved primarily for the treatment of hypertension and heart failure. In July 2018, Defendants, with guidance from the FDA, began announcing voluntary recalls of certain VCDs after trace amounts of a previously unknown nitrosamine class impurity, N-nitrosodimethylamine ("NDMA"), were detected in some, but not all, lots of valsartan.[4] As the FDA has noted, NDMA is common "in water and foods, including cured and grilled meats, dairy products and vegetables."[5] In December 2018, companies began recalling specific batches of two other ARBs, losartan

[3] Plaintiffs' Co-Lead Counsel includes Ruben Honik of Honik Law, P.C., Daniel Nigh of Levin Papantonio, Thomas, Mitchell, Rafferty, Proctor, P.A., Adam Slater of Mazie Slater Katz & Freeman, LLC, and Conlee Whiteley of Kanner & Whiteley, LLC. *See* [Dkt 96] Case Management Order No. 6 Approving Plaintiffs' and Defendants' Leadership Structure.

[4] *See* FDA Announces Voluntary Recall (2018) FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity | FDA

[5] *See* FDA Information about Nitrosamine Impurities In Medications Information about Nitrosamine Impurities in Medications | FDA (also stating "[e]veryone is exposed to some level of nitrosamines" and "[n]itrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer.")

and irbesartan, for possible trace amounts of N-nitrosodiethylamine ("NDEA"). A small number of losartan batches were recalled for potentially containing a third impurity, N-Nitroso-N-Methyl-4-aminobutyric acid ("NMBA"). The recalls resulted in an investigation by the FDA and the identification of API manufacturing processes that likely led to the presence of NDMA and/or NDEA in valsartan API. The FDA ultimately issued its first official guidance with regard to nitrosamines in September 2020, more than two years after the initial recalls.[6] The FDA has estimated the additional risk posed by ingesting recalled valsartan medications at one additional case of cancer for every 8,000 persons consuming the recalled medications at the highest potential dose daily for four years.[7] The FDA repeatedly issued statements with each recall at issue substantively, noting that the "risk to patients taking affected products is **extremely low**" and recommending that patients continue taking their current medication, even if recalled, until their healthcare provider prescribed a replacement due to the low risk posed. [8]

III. PLEADINGS

Plaintiffs consolidated their claims into three Valsartan Master Complaints: two putative nationwide class actions asserting medical monitoring and economic loss claims and one personal injury complaint asserting product liability claims sounding in negligence, strict liability, breach of warranty, fraud, and consumer protection. *See* [Dkt. 123] Amended Medical Monitoring Master Complaint; [Dkt. 398] Second Amended Economic Loss Master Complaint; [Dkt. 122] Personal Injury Master Complaint.[9] Personal

[6] *See* Control of Nitrosamine Impurities in Human Drugs – Guidance for Industry.

[7] *See* Statement on the agency's ongoing efforts to resolve safety issue with ARB medications | FDA (2019), https://www.fda.gov/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (last visited Feb 5, 2021).

[8] *See* FDA Statement on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue (2019), https://www.fda.gov/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys (last visited Feb. 9, 2021)

[9] Plaintiffs similarly consolidated their claims into Irbesartan and Losartan Master Complaints. *See* [Dkt. 751] Master Losartan Economic Loss Class Action Complaint; [Dkt. 680] Master Irbesartan Economic Loss Class Action Complaint; [Dkt. 681] Master Losartan Medical Monitoring Class Action Complaint; [Dkt. 682] Master Losartan Personal Injury Complaint; [Dkt. 683] Master Irbesartan Personal Injury Complaint; [Dkt. 752] First Amended Consolidated Irbesartan Economic Loss Complaint.

injury plaintiffs also file individual Short Form Complaints. *See* [Dkt. 187] Case Management Order No. 13.[10] A plaintiff may also direct file their complaint into the MDL. *See* [Dkt. 76] Case Management Order No. 3.[11]

IV. DEFENSES

a. Motions to Dismiss

Defendants filed motions to dismiss on all counts once Judge Kugler permitted such motions.[12] Judge Kugler has, to date, issued five (5) separate opinions addressing Plaintiffs' claims. *See* [Dkt. 675] MTD Opinion 1; [Dkt. 728] MTD Opinion 2 ; *See* [Dkt. 776] MTD Opinion 3; [Dkt. 818] MTD Opinion 4; [Dkt. 838] MTD Opinion 5. Certain claims were dismissed with prejudice either in their entirety (Magnuson-Moss Warranty Act claims) or as to specific defendants or states depending on the state law at issue. Others were dismissed without prejudice and Plaintiffs have advised they intend to seek leave to amend. Plaintiffs' motions for leave to amend are due by March 3, 2021. *Id*. The Parties agreed upon a process by which Defendants that were deemed "peripheral" in this litigation, e.g. repackagers, can seek dismissal without prejudice from this litigation after the production of documents detailed within the Order. Certain of the smaller re-packagers and retailers have been dismissed without prejudice pursuant to the peripheral defendant dismissal order. *See* [Dkt. 248] Stipulated Conditional Order of Dismissal Without Prejudice.

b. General Causation and *Daubert*

Plaintiffs have the burden of establishing General Causation in all the actions — this key battle is first

[10] The Court ordered all plaintiffs with currently-filed personal-injury cases to file a Short Form Complaint, the form of which was approved in Case Management Order No. 13. *See* [Dkt. 187] Case Management Order No. 13, entered on August 20, 2019. Personal injury direct filed cases in the MDL were ordered to use the Short Form Complaint. *See* [Dkt. 187] CMO 13; *see also* [Dkt. 234] CMO 13(a) (attaching amended version of operative Short Form Complaint).

[11] The direct file process was expanded to include Losartan and Irbesartan complaints. *See* [Dkt. 376] CMO No. 19.

[12] "No personal jurisdiction motions may be filed without leave of court" and those defenses are reserved. *See* [Dkt. 726] Revised CMO 22.

up. *See* Transcript of November 24, 2020 Status Conference at 12:18-13:1 ("I do agree with defense counsel that I'm not going to decide class certification until after the *Daubert* decisions are made, because if --- the defendants are correct and **if the plaintiffs cannot demonstrate general causation, then there's really no purpose in class action**. But you're going to be doing discovery on those issues of class certification so that if plaintiff's experts survive the Daubert, then we can move immediately into class certification motions and decide those motions at that time."). General causation requires Plaintiffs to establish that the nitrosamine impurities, at the trace levels detected, and at the exposure rate for the periods ingested, ***can and did specifically cause their alleged cancers.*** As Judge Kugler explained "[t]here's a number of people who claim I understand that they've contracted cancer from taking this drug. It's probably going to be a heavy lift to prove that […] I think that causation carries over into the other cases that are pending because, you know, if the contamination is not dangerous, then maybe you don't have such a great argument that you should get your money back for paying for it." *See* [Dkt. 77] Transcript of March 27, 2019 Case Management Conference at 5:9-16.[13] The Court reasoned "[t]here has to be a reckoning at some point as to all these cancer claims, and they can't -- I don't think at the end of the day the science is going to support this thinking, this theory -- well, it's not even a theory of the plaintiffs, but the claims of some of these plaintiffs that every conceivable cancer out there is caused by the impurities in the valsartan-containing drugs. And there is going to have to be a winnowing of that, and there's going to be a focus by the plaintiffs on what actual cancers they claim have been caused or will be caused in the future by these valsartan-containing drugs… there has to be a reckoning, a day of reckoning, as to these cancer claims, and it can't go on forever." *See* [Dkt. 636] Transcript of July 29, 2020 Case Management Conference at 43:21-44:6, 44:16-18.[14] Defendants anticipate this battle culminating in

[13] Judge Kugler noted, experts will "be opining on all leading up to the *Daubert* motions on which much of this case hangs." See [Dkt. 77] Transcript of March 27, 2019 Case Management Conference at 11:22-25. "We're all obviously all aiming towards the day of reckoning which is going to be the *Daubert* motion when the Court's going to be called upon to decide the experts and the General Causation issue and who can testify about that." *See* Transcript of April 29, 2020 Case Management Conference at 30:24-31:3.

[14] Judge Kugler ordered the plaintiffs to disclose "the types of cancer for which they will provide expert reports to proceed to the general causation Daubert hearing in the MDL" no later than December 31, 2020. *See* [Dkt. 726] Revised CMO 22.

numerous expert challenges and a significant general causation *Daubert* hearing.

c. Class Certification

Should this litigation survive past general causation, a second key battleground will be over class certification as to both the economic loss and medical monitoring class actions. The Court will hear *Daubert* motions as to the parties' class certification experts in Summer of 2022. While Judge Kugler indicated that the putative class actions will take trial priority, that will appropriately occur only if the class claims survive both general causation and class certification rulings. *See* Transcript of November 24, 2020 Case Management Conference at 13:6-7 ("We'll do [class certification] in due course after we have a full airing of the general causation issues.").

V. OPERATIVE SCHEDULING ORDER

The Court recently approved a 60-day extension to the deadlines set forth in Revised Case Management Order No. 22 ("CMO 22") which governs the sequencing of discovery. *See* [Dkt. 843] Special Master Order 2; *see also* [Dkt. 726] Revised Case Management Order No. 22. The personal injury cases will be worked up simultaneously with the putative class actions for purposes of discovery. The Order staggers fact discovery into two phases. During Phase I, which focuses on general causation, the parties must complete the depositions of all putative class representatives, ten personal injury bellwether plaintiffs, and the Defendants' 30(b)(6) and individual fact witnesses.[15] *Id.* Thereafter, the parties commence expert discovery on general causation. *See* [Dkt. 726] Revised Case Management Order No. 22. During Phase II, the parties must complete the depositions of the remainder of personal injury bellwether plaintiffs; third parties, including medical providers and any third-party entities such as

Plaintiffs' disclosure listed at least 13 different potential cancers: bladder, blood, breast, colorectal/intestinal, esophageal, gastric, kidney, liver, lung, pancreatic, pharyngeal, prostate and uterine cancer. *See* [Dkt. 706] Disclosure.

[15] This Court recently modified certain deadlines within CMO 22, ordering the parties to submit a schedule for depositions no later than February 17, 2021, "with the understanding that counsel will cooperate to avoid double-and triple-tracking of depositions and that all depositions on general causation will be completed by June 1, 2021." *See* [Dkt. 843] Special Master Order 2.

vendors; any new putative economic loss class representatives allowed by the Court; and further discovery, if any, of wholesaler and retailer/pharmacy defendants.

VI. PLAINTIFFS' DISCOVERY

Plaintiffs' fact sheets and authorizations must be completed by all putative class representative and personal injury plaintiffs. *See* [Dkt. 114] Case Management Order No. 7 .[16] Judge Schneider also ordered requests for production for putative class representatives to be responded to without objection. *See* [Dkt. 633] CMO No. 21."[17] Defendants intend to serve Rule 34 discovery on personal injury bellwether plaintiffs and are conferring with Plaintiffs over those requests. Defendants are also serving requests for dismissal of Defendants named in the short form complaint and/or plaintiff fact sheet, but for which no corresponding product ID evidence has been provided for the named Defendant(s).

VII. DEFENDANTS' DISCOVERY

There are separate fact sheets for each "category" of Defendants: Pharmacy, Wholesaler/Repackager/Relabeler, Finish Dose Manufacturer, and API Manufacturing *See* [Dkt. 546] Order Approving Fact Sheets to be Answered by Defendants. The DFS process intends to identify the supply chain from the Plaintiff to the API Manufacturer through a series of rolling deadlines. *See* [Dkt. 452] Order. Defendants are in the process of preparing DFSs for certain class representative and personal injury plaintiffs. Judge Schneider also ordered certain Defendants[18] to produce "core discovery" early in the litigation, "to get in plaintiffs' hands early in the case key information to enable plaintiffs to focus and

[16] A show cause process instituted by the Court for deficient plaintiff fact sheets has alone resulted in the dismissal of numerous claims and that process continues.

[17] Plaintiffs recently served responses to the requests simply stating "Plaintiffs will produce responsive non-privileged documents, if any, in their possession *See* Plaintiffs' Amended Responses to Defendants' First Set of Requests for Production of Documents to Economic Loss Class Action Plaintiff (Jan. 4, 2021).

[18] The "Core Discovery Defendants" were the API and finished dose manufacturers and the FDA liaisons for those foreign manufacturing defendants who had not been served at the time of core discovery. Plaintiffs also identified numerous other entities subject of document subpoenas. The parties are in the process of briefing the Manufacturer Defendant's purported possession, custody, and control over these documents. *See* [Dkt. 727] Order; *see also* [Dkt. 766] Defendant's Letter1.

narrow their discovery requests." *See* [Dkt. 88] MDL Order Regarding Core Discovery; *see* 11/20/19 Tr. at 12:5-8. The "core discovery" production was completed on June 27, 2019, except as to any required supplementation relating to ongoing regulatory communications.

The parties heavily negotiated an ESI protocol, which was entered by the Court on June 19, 2019. *See* [Dkt. 127] Case Management Order No. 8; *see also* [Dkt. 493] Stipulation Pertaining to Teva Defendants. The parties negotiated, and Judge Schneider approved, a set of custodians, a list of ESI search terms, and a set of Rule 34 document requests for the Manufacturer Defendants.[19] These custodians and search terms are finalized, with leave to amend only upon a showing of good cause. Productions of Manufacturer Defendants' responsive documents were made on a rolling basis from July 15, 2020 through November 30, 2020, resulting in production of millions of pages, even before motions to dismiss have been fully decided.[20] Written discovery as to API and finished dose manufacturers is largely complete. To the extent that a large percentage of Manufacturer Defendants' documents were produced later in the production period, that was the unavoidable result of the extensive redaction and privilege review workstreams that had to be completed near the end. Teva and Mylan utilized TAR/CMML in their document review and production and engaged in extensive negotiations with Plaintiffs over the terms of their respective validation protocols. After a series of arguments and proposals, including input from Teva's ESI consultant Dr. Maura Grossman, Judge Schneider ultimately approved Teva's validation protocol, which requires Teva's final production on February 15, 2021. *See* [Dkt. 695] Order.

Privilege logs are due 30 days after the production. *See* [Dkt. 564] Order. This Court ordered that by February 15, 2021, Plaintiffs must identify any privilege log they claim is inadequate and the reasons for

[19] *See* [Dkt. 485] Stipulation Pertaining to Mylan Defendants; [Dkt. 487] Stipulation Pertaining to ZHP Defendants; [Dkt 489] Stipulation Pertaining to Hetero Defendants; [Dkt. 490] Stipulation Pertaining to Torrent Defendants; [Dkt. 493] Stipulation Pertaining to Teva Defendants; [Dkt. 328] Order Entering Custodians; [Dkt 324-1] Plaintiffs' Second Amended Set of Requests.

[20] Judge Kugler also entered a Confidentiality and Protective Order on June 26, 2019 establishing a protocol for designating confidential documents. *See* [Dkt. 139] Confidentiality and Protective Order,

the claimed inadequacy. Thereafter counsel shall meet and confer and report to the Court by February 22, 2021 on their efforts to resolve privilege log disputes. *See* [Dkt. 843] Special Master Order 2.

VIII. DOWNSTREAM DEFENDANTS DISCOVERY

The Downstream Defendants comprise nine Pharmacy Defendants and three Wholesaler Defendants, each of whom has been named as a defendant solely by virtue of having sold VCDs.[21] The claims against these Defendants are incidental to the main claims against the manufacturers, and the Court has recognized that discovery against these Defendants should be narrowly tailored to reflect that.[22] The Downstream Defendants' document productions in response to Plaintiffs' first set of requests are substantially complete. They have also produced DFSs for the class representatives and for Plaintiffs' initial group of personal injury plaintiff picks, identified in August 2020.[23] The recent Rule 12 rulings further narrow the scope of litigation against—and any potential additional discovery that Plaintiffs might seek from—the Pharmacy and Wholesaler Defendants.

IX. DEPOSITIONS

The parties negotiated, and the Court entered a fact witness deposition protocol governing the depositions of the parties and their witnesses. *See* [Dkt. 632] Case Management Order No. 20; *see also* [Dkt. 604] Letter. Defendants also intend to work with Plaintiffs on a protocol for treating physician

[21] Plaintiffs current complaints plead no basis for actual or constructive knowledge of the substantive manufacturing issues forming the bases of the complaints.

[22] For example, when the Retailer Defendants raised concerns about the scope of Plaintiffs' proposed 65 document requests (with more than 150 discrete subparts on 15 topics), Judge Schneider struck the complete set of Requests as "not consistent with the Court's intent and spirit about the discovery to be directed to the non-manufacturing defendants." (Dec. 18, 2019 email).

[23] To date, the Pharmacy Defendants have produced vast amounts of data, including their policies and procedures relating to recalls, the recall notifications they received and distributed, and data reflecting all purchases and dispensed fills of the VCDs going back to 2012. The Wholesalers have made similar document productions, and also produced voluminous data reflecting all purchases and sales of the VCDs at issue in this litigation going back to 2012. Judge Schneider declined Plaintiffs' request to order the Downstream Defendants to produce pricing and profit information (*i.e.*, what pharmacies or wholesalers paid for VCDs and the profits they realized from those sales) ruling that the pricing and profit information Plaintiffs sought was "not directed to the core issues in the case and [would] be the subject of defendants' motions to dismiss" and deferred those requests until Rule 12 motions were decided. *See* Transcript of July 6, 2020 Hearing at 88:2-7.

communications and depositions. Defendants have taken eight of the economic loss and medical monitoring class representatives' depositions, have scheduled an additional twenty-one depositions of the medical monitoring, economic loss and third party payor plaintiffs and are coordinating with Plaintiffs to schedule depositions of the twenty-eight personal injury bellwether plaintiffs.[24] The scheduling and sequencing of Defendants' witnesses has been complicated by the fact that many of the witnesses are outside of the United States, including locations where depositions are difficult to schedule, if not prohibited.[25] The parties are currently in the process of taking and scheduling Rule 30(b)(6) Deposition of the Manufacturer Defendants in compliance with Revised CMO 22 and this Court's February 4, 2021 order. *See* [Dkt. 843] Special Master Order 2.

X. STATE CASES AND COORDINATION

There are fifteen (15) cases pending in New Jersey State Court that mirror the claims asserted in the MDL. The cases were filed in Middlesex County, but Plaintiffs have not served all Defendants. The state court entered consent agreements between certain parties to stay the claims against the served entities pending a Multi-County Litigation application. *See e.g.* Consent Order. Of immediate focus is this Court entering a Coordination Order to coordinate discovery among the MDL and any State Court actions.

In conclusion, we greatly appreciate your willingness to review these materials. Should you have any questions or need any additional information, please do not hesitate to contact me.

With Best Regards,

/s Lori G. Cohen
Lori G. Cohen, Esq.
Attorney for Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.

[24] Defendants have encountered some challenges in obtaining complete records from third-parties in time for some depositions and had to proceed with the depositions of some of the class representatives without complete records. The parties selected a pool of twenty-eight (28) personal injury plaintiff bellwether cases on January 15, 2021. The Parties are still meeting and conferring over the language of a proposed order memorializing these selections but are nevertheless already coordinating on setting these depositions.

[25] The Parties worked together on protocols governing the depositions in this case for Chinese Nationals Residing in Mainland China and Indian Nationals Residing in India. *See* [Dkt. 701] Order.

cc:
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